AUG 27 2003

510(k) Summary K031187

Date Summary Prepared

April 4, 2003

Submitter's Name and Address

Philips Medical Systems
Cardiac and Monitoring Systems
Cardiac Resuscitation
3000 Minuteman Road
Andover, MA 01810-1099

Contact Person

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Cardiac and Monitoring Systems
Cardiac Resuscitation
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Device Name

Proprietary Name:	HeartStart MRx
Common Name:	Defibrillator/Monitor
Classification Names:	Low-Energy Defibrillator, Arrhythmia Detection & Alarms (Automatic External Defibrillator), External Transcutaneous Pacemaker (noninvasive), ECG, Non-Invasive Blood Pressure, End Tidal Carbon Dioxide, Pulse Oximeter, and Cardiac Monitor.

Predicate Devices

The legally marketed devices to which Philips Medical Systems claims equivalence for the HeartStart MRx are as follows:

- Philips Medical Systems (formally Agilent Technologies) Heartstream XL Defibrillator/Monitor, and
- ZOLL Medical Corp. M Series Defibrillator

The design of the HeartStart MRx is substantially equivalent in safety and performance to the devices listed above.

Device Description

The HeartStart MRx is a lightweight, portable external defibrillator, offering two modes of operation for defibrillation: manual mode and semi-automatic mode (AED).

In manual mode, the HeartStart MRx is a full-featured manual defibrillator, designed for use by clinicians trained in Advanced Cardiac Life Support (ACLS). Manual operation

allows users to select energy levels for external and internal defibrillation, perform synchronized cardioversion and provide non-invasive external pacing.

In AED mode, the HeartStart MRx, allows the provider who is trained in Basic Life Support (BLS) to provide defibrillation therapy. The device analyzes a patient's rhythm and advises the user to provide a shock. Voice prompts guide the user through the defibrillation process by providing instructions and patient information. The voice prompts are reinforced by messages that appear on the display.

In both modes of operation, the HeartStart MRx utilizes impedance compensating biphasic truncated exponential therapy waveform.

The HeartStart MRx can also be used for ECG monitoring of a patient using either 3 or 5 lead cables.

Additionally, the HeartStart MRx is offered with the following optional functionality:

Non-Invasive External Pacing:

The pacing option is intended for treating patients with symptomatic bradycardia. This parameter is used by ACLS trained clinicians typically performed in a hospital environment.

12-Lead ECG:

The 12-Lead ECG option is intended to provide a conventional diagnostic 12-Lead ECG report, which may include measurements and interpretative statements. This parameter is used in both the hospital and pre-hospital environment by ACLS and BLS trained clinicians.

Non-Invasive Blood Pressure:

The NIBP option is intended for noninvasive measurement of a patient's arterial blood pressure. This parameter is used in both the hospital and pre-hospital environment by ACLS and BLS trained clinicians.

Endtidal CO2:

The EtCO2 option is intended for noninvasive monitoring of a patient's exhaled carbon dioxide and also provides a respiration rate. This parameter is used by ACLS trained clinicians and performed in both the pre-hospital and hospital environments.

Pulse Oximetry:

The SpO2 option is intended for use when it is beneficial to assess a patient's arterial oxygen saturation level. This parameter is used by trained clinicians and performed in both the pre-hospital and hospital environments.

Features

- ECG monitoring through pads or separate monitoring electrodes
- Alarms on Heart Rate Limits and shockable rhythms
- Built-in strip chart printer
- Display for viewing waveforms and messages

- Automated self test with indicator
- Internally stored event summary which may be printed
- Voice prompts in AED mode
- Adjustable ECG size
- Adjustable volume control
- Setup mode, automatic self tests and error handling
- Lithium Ion battery
- Internal Defibrillation
- External Paddles with patient contact indicator
- 3, 5, and 12 Lead ECG cables
- Battery Charging Kit
- PCMCIA Data card for data and event capture
- Data recording, management, and transfer
- Event Review
- AC Power Module
- DC Power Module

Intended Use

The HeartStart MRx is for use for the termination of ventricular tachycardia and ventricular fibrillation.

The device is for use by qualified medical personnel trained in the operation of the device and qualified by training in basic life support, advanced cardiac support, or defibrillation. It must be used by or on the order of a physician.

The SMART Biphasic waveform utilized in the Heartstream XL Defibrillator/Monitor has previously undergone clinical testing in adults. These trials support the waveform's effectiveness for defibrillation of ventricular tachyarrhythmias at 150J. There are currently no clinical studies related to the use of SMART Biphasic waveform in pediatric applications.

Manual Defibrillation: Asynchronous defibrillation is the initial treatment for ventricular fibrillation and ventricular tachycardia in patients that are pulseless and unresponsive. Synchronized defibrillation is indicated for termination of atrial fibrillation.

AED Therapy: To be used in the presence of a suspected cardiac arrest on patients of at least 8 years of age that are unresponsive, not breathing and pulseless.

Non-Invasive External Pacing:

The pacing option is intended for treating patients with symptomatic bradycardia. It can also be helpful in patients with asystole, if performed early.

12-Lead ECG:

The 12-Lead ECG option is to be used where the clinician decides to evaluate the electrocardiogram of adult and pediatric patients as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment or to rule out causes for symptoms.

Non-Invasive Blood Pressure:

The NIBP option is intended for noninvasive measurement of arterial blood pressure for adult and pediatric patients.

Endtidal CO_2:

The $EtCO_2$ option is intended for noninvasive monitoring of exhaled carbon dioxide and to provide a respiration rate for adult, pediatric and neonatal patients.

Pulse Oximetry:

The SpO_2 option is intended for use when it is beneficial to assess the oxygen saturation level for adult and pediatric patients.

The HeartStart MRx is a fully featured, external defibrillator/monitor intended for use by qualified medical personnel, trained in either Advanced Cardiac Life Support or Basic Life Support, in a hospital or pre-hospital environment.

Comparison of Technology Characteristics

The HeartStart MRx employs the same fundamental scientific technologies as the commercially available predicate devices used for comparison. The HeartStart MRx acquires and analyzes ECG signals, utilizes the same shock advisory criteria, and advises the user to deliver a shock when required utilizing voice prompts as in the Heartstream XL. Heart rate alarms, noninvasive pacing and pulse oximetry functions are provided, as in the Heartstream XL. The HeartStart MRx's 12-Lead ECG, NIBP, and EtCO2 technologies are substantially equivalent to the ZOLL M Series defibrillator.

Tests Used in Determination of Substantial Equivalence

The tests used in the determination of substantial equivalence included only bench testing. Bench testing includes hardware and software testing demonstrating that the performance of the device meets its specification

Conclusion from Testing

Based on the results of the testing described above, it is concluded that the HeartStart MRx does not raise any different questions regarding the safety or effectiveness as compared with the predicate devices. It is considered to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2003

Phillips Medical Systems
c/o Mr. Peter Ohanian
Director, Quality and Regulatory Affairs
3000 Minuteman Road, MS 0222
Andover, MA 01810

Re: K031187
Heartstart MRX, Model M3535A
Regulation Number: 870.1025, 870.5300, 870.5550
Regulation Name: Arrhythmia Detector and Alarm, DC-defribrillator, External Transcutaneous cardiac pacemaker
Regulatory Class: Class III
Product Code: MKJ, LDD, DRO
Dated: July 24, 2003
Received: July 29, 2003

Dear Mr. Ohanian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use K031187

510(k) Number (if known): K031187

Device Name: Philips Medical Systems, HeartStart MRx

Indications for Use: The HeartStart MRx is for use for the termination of ventricular tachycardia and ventricular fibrillation.

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Pulse Oximetry:

The SpO_2 option is intended for use when it is beneficial to assess the oxygen saturation level for adult and pediatric patients.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031187